AKZO NOBEL

Organon Inc.

Via Fax and Regular Mail

February 23, 1998

Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects
Washington, D.C. 20231

Re: U.S. Patent No. 5,270,057

Dear Ms. Tyson:

Reference is made to your correspondence dated January 12, 1998 to Ronald Wilson, Director, Health Assessment Policy Staff, Office of Health Affairs, of the Food and Drug Administration ("FDA"), regarding an application for patent term extension of the above-referenced patent. That patent covers a product marketed in the U.S. by Organon Inc. ("Organon") under the trade name "Follistim™ (r-FSH "follitropin beta").

You have stated:

> "The regulatory review period in the application for patent term extension for U.S. Patent No. 5,156,957 includes an IND submitted to the FDA on January 24, 1992. It is noted that no IND has been claimed in the application for patent term extension for U.S. Patent No. 5,270,057, but if the testing done by Serono Laboratories Inc. was relied upon by FDA in approving the new drug application (No. 20-582) for FOLLISTIM™, then the regulatory review period cannot be considered to be different than that for GONAL-F."

Organon's Response:

You correctly point out that no IND was submitted for Follistim™. This was so for a simple reason. Organon conducted its clinical testing for Follistim™ solely outside the U.S., which obviated the necessity for filing an IND for Follistim™. As for Organon's response to the more substantive point you have raised above, please be advised that it is Organon's understanding and belief that the FDA only relied upon the data submitted in New Drug Application ("NDA") No. 20-582 in approving that application. In that regard, you should be aware that Organon's NDA No. 20-582 did not contain any data from any study, animal, human or otherwise, using Serono Laboratories Inc.'s ("Serono") Gonal-F® because Organon did not and does not have access to such data. Likewise, Serono's NDA

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for Gonal-F® did not contain any data from any study, animal, human or otherwise, using Organon's Follistim™ because Serono did not and does not have access to such data. Organon believes that FDA relies on the data submitted in each particular NDA to decide whether or not to approve such NDA. Consequently, it is Organon's position that the regulatory review period for Follstim™ must be considered as different from that of Gonal-F®.

Please feel free to contact me with any questions regarding the foregoing.

Respectfully submitted,

Patrick J. Osinski
Vice President

cc: Ronald Wilson
William M. Blackstone, Esq.